JUN 1 8 2002

510(k) Summary

K011676

General Information

Classification	Class II
Trade Name	VivaWave™ Microwave System
Submitter	Vivant Medical, Inc. 1916-A Old Middlefield Way Mountain View, CA 94043 650-694-2900
Contact	Steven Kim Director of Research and Development

Intended Use

The VivaWave™ Microwave System is intended for coagulation of soft tissue

Predicate Devices

HSE-5M Microtaze - Cooper Lasersonics, Inc.	K864413
HHS-15M Microtaze - Cooper Lasersonics, Inc.	K861904
RF-2000 RF Generator - RadioTherapeutics Corp	K981672
LeVeen Needle Electrode - RadioTherapeutics Corp	K962313
Model 30-6 Multielectrode Array Probe - Zomed Intl	K962692

Device Description

The VivaWave™ Microwave System consists of an external microwave generator and probe. The generator is manually set at the desired power levels by the operator. Procedure time is also preset by the operator. The generator is connected to the probe through a connector.

The external generator unit measures approximately (13"H x 17"W x 3.5"D) The exterior housing is formed of aluminum coated with plastic.

The unit contains electric circuits, circuit boards, and integrated control panel. The major components of the generator are cooling fans, power supply, microwave module and the front panel/control board assembly.

The probe is a specifically designed antenna coated with Teflon (PTFE). The probe is permanently attached to a cable that carries the energy from the generator to the tip of the probe. The proximal end of the cable has a connector that fits into the generator and allows the energy to be delivered to the probe.

Materials

All patient contact materials used in the manufacture of the VivaWave™ Microwave System are suitable for this use and have been used in numerous previously cleared products.

Testing

The generator is designed to comply with electrical safety (EN60601-1) and electromagnetic compatibility (EN60601-1-2). Product testing was conducted to evaluate conformance to product specification. Biocompatibility testing was conducted in accordance with ISO 10993. All materials used in the VivaWave™ Microwave System are biocompatible and suitable for use.

Summary of Substantial Equivalence

The VivaWave™ Microwave System is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Vivant Medical believes the VivaWave™ Microwave System is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2002

Mr. Steven Kim
Director, Research & Development
Vivant Medical, Inc.
1916-A Old Middlefield Way
Mountain View, CA 94043

Re: K011676
Trade/Device Name: VivaWave™ Microwave System
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NEY and GEI
Dated: May 8, 2002
Received: May 9, 2002

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

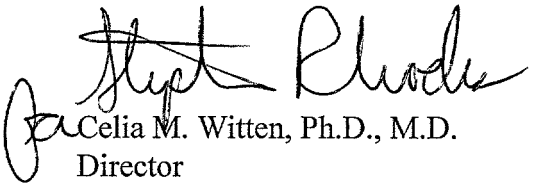
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): This application K011676

Device Name: VivaWave™ Microwave System

Indications for Use: The VivaWave™ Microwave System is intended for coagulation of soft tissue

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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